REMARKS

35 U.S.C. §102(b)

The Examiner rejects claims 1, 3-5, 9 and 17-20 under 35 U.S.C. §102(b) as being anticipated by Felzmann et al (2001). Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

Applicants submit that for the reasons of record, Felzmann 2001 does not anticipate the present invention because it does not teach every limitation of the claims.

Applicants also submit that the cancer vaccine therapy alleged to be disclosed in Felzmann 2001would not have enabled one of skill to practice the method of the present invention. Applicants submit that Felzmann (2001) is not enabling because, as discussed in the Declaration of Dr. Thomas Felzmann dated May 13, 2008 (enclosed herein), and contrary to the Examiner's assertions, the DCs were NOT loaded with tumor antigen, but EBV. (See Declaration page 6, bullet point 11, last paragraph). The Examiner points to language in Felzmann 2001 on pages 153, column 1, last paragraph of Discussion, indicating that "it *might* be feasible to use DCs maturated *with transgenic CD40L accessory cells* for the in vitro expansion of antigen-specific T lymphocytes, using soluble target cell lysates. These can be prepared *in principle* from any tumor." However, the Examiner is basing his rejection on mere speculation that it *might* be feasible, and that it *might* be feasible ONLY IF the DCs were "maturated *with transgenic CD40L accessory cells.*" Based on this disclosure, one of skill would NOT be able to make the cells of the present invention (using LPS and tumor antigens) and administer those cells as a tumor vaccine with any expectation of success without undue experimentation. Thus, Applicants submit that the disclosure is not sufficient to anticipate the present invention.

Furthermore, Felzmann 2001 would not enable one of skill to make and use the present invention without undue experimentation because the experiments of Felzmann 2001 were not suitable to establish the fact that DCs may be used in the context of a cancer vaccine. As the Declaration indicates, knowledge of the unsuitability of the treatment in Felzmann 2001 for cancer vaccines

is shown by the lack of data regarding killer cell assays. The Declaration states that it was essentially impossible to draw any conclusions about the development of a cytolytic anti-tumor automimmune response from the data disclosed in Felzmann 2001. Additionally, Felzmann 2001 did not suggest or teach the use of LPS (as opposed to CD40) in a method of tumor vaccination. As discussed in the Declaration, the use of LPS in a *clinical setting* without causing harm to the patient was not considered or understood in the community because LPS is a bacterial endotoxin. (Declaration page 5, paragraph 2).

Applicants also point out that the disclosure of Felzmann 2001 teaches away from the present invention beause the initiation of an immune response based on killer cells is only possible during the 24 hour time window in which IL-12 is secreted from the DCs. As the Declaration indicates, "a short exposure of DCs to a PAMP/danger signal is sufficient to initiate the differentiation program of DCs." (Declaration page 7, paragraph 13). Based on the disclosure in Felzmann 2001, one of skill would not have been able to make and use the present invention for its intended purpose without undue experimentation.

Additionally, Felzmann 2001 did not suggest or teach to one of skill in the art to use LPS (as opposed to CD40) in a method for tumor vaccination without undue experimentation. As discussed in the Declaration, the use of LPS in a *clinical setting* without causing harm to the patient was not considered or understood in the community because LPS is a bacterial endotoxin. (Declaration page 5, paragraph 2). Thus one of skill would not consider the use of an endotoxin in the treatment of an already immune-challenged patient.

Applicants submit that *even if* the prior art lists each element of the claims (by a patchwork combination of the experimental cells of interest and the control cells and pure speculation), it does not provide enabling disclosure for the present invention. Applicant respectfully request that the Examiner withdraw the rejection.

35 U.S.C. §103

The Examiner rejects claim 2 under 35 U.S.C. §103 as unpatentable over Felzmann (2001) in view of Asavaroengchai et al. The Examiner rejects claims 6-8 under 35 U.S.C. §103 as unaptentable over Felzmann (2001) in view of Rieser, and further in view of Felzmann (2000). Applicants submit that Felzmann 2001 alone does not disclose every limitation of the claims, and neither Asavaroengchai, Rieser, or Felzmann 2000 remedy those deficiencies for the reasons of record and for the reasons discussed above. Applicants request that the Examiner withdraw the rejection.

CONCLUSION

In view of the above remarks, Applicants request the Examiner withdraw all rejections.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By

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